

REMARKS

I. **Statement**

A personal Examiner interview was held on December 9, 2004. During the interview, currently pending independent claim 17 was discussed in view of the rejections under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with written description and enablement requirements.

The Examiner stated that the specification did not provide any data regarding treating arthritis or symptoms associated with arthritis and therefore, was not enabling. The Examiner then proposed ways in which the claims could be amended so that they may be enabled, such as converting the claims to product claims or claiming a method for lubricating joints. When Applicant's representatives suggested amending the claim to a "method of augmenting or replacing the function of cartilage or synovial fluid," the Examiner agreed that that may be allowable so long as the language was supported in the specification.

The Examiner also stated that the amended claim would have to include where the hydrogel was being placed. Applicant's representatives suggested "in the joint" because "intra-articular cavity" may not include the synovium. The Examiner was amenable to including "in the joint" so long as support could be found in the specification.

Finally, Applicant's representatives pointed out that U.S. Patent No. 5,798,096 had been accidentally overlooked and was not previously submitted in an Information Disclosure Statement. The reference is a U.S. national phase application of a PCT Application, PCT/UA94/00022, and is apparently an equivalent of an European patent application, EP 0742022 A1, both of which had been previously submitted by Applicant. However, it was then realized that the reference had, in fact, been previously submitted

in an Information Disclosure Statement filed on April 7, 2004 and initialed by the Examiner as having been considered on September 1, 2004.

II. Amendment

Reconsideration of rejections in this application is respectfully requested. Upon entry of the foregoing amendment, claims 17-26 and 36-39 are pending in the Application. Claims 17, 18 and 39 are amended.

Applicant respectfully requests entry of the above amendment and submits that the amendment does not introduce new matter or new issues. Support for the amendment to claims 17 and 39 can be found throughout the specification (considered as a whole) and in the claims as originally filed. For example, support for the amendment to claim 17 can be found, *inter alia*, in claims 17 and 29 as originally filed and in the specification at page 4, lines 9-11; page 7, lines 30-32; page 8, lines 9-10; page 8, line 34 to page 9, line 1 and page 9, lines 21-26. Support for the amendment to claim 39 can be found, *inter alia*, in claim 39 as originally filed, and in the specification at page 6, lines 1-3. Claim 18 is amended for punctuation.

Based on the above amendment and the following remarks, Applicant respectfully requests that the Examiner reconsider all outstanding rejections and that they be withdrawn.

III. Claim Rejections Under 35 U.S.C. § 112

Claims 17-26 and 36-39 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Claims 17-26 and 36-39 are also rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement.

First, it was stated in the Office Action that claims 17-26 and 36-39 contain subject matter which was not described in the specification so as to reasonably convey

to one skilled in the art that the inventor had possession of the claimed invention when the application was filed. It was asserted that there are no method steps presented for the treatment of arthritis and no specified symptoms of arthritis to be treated although it was admitted that arthritis symptoms are well known. See Office Action, pp. 2-3. In addition, it was stated that no clinical or *in vitro* data is present to support the use of the polyacrylamide endoprosthesis as a treatment of arthritis.

Second, it was stated that claims 17-26 and 36-39 contain subject matter which was not described in the specification so as to enable one skilled in the art to make and/or use the invention. It was asserted that 1) the prior art did not teach the use of hydrogel for treating arthritis although it teaches the hydrogel as an endoprosthesis, 2) the claims broadly claim a treatment of arthritis without specifying symptoms to be treated, 3) the specification does not provide guidance as to how the treatment is to be accomplished, 4) the specification does not include examples or information regarding *in vivo* or *in vitro* studies of the treatment and 5) the ordinary practitioner would have to perform tests to determine how the endoprosthesis treats arthritis and its associated symptoms.

Applicant respectfully traverses these rejections. Applicant continues to maintain that his disclosure satisfied the written description requirement for claim 17 and the remaining rejected claims, which depend from claim 17, prior to the amendment herein. Skilled artisans familiar with the disclosure would have readily realized that Applicant possessed the subject matter of those claims at the time the application was filed.

For example, symptoms of arthritis are well known in the art, as acknowledged in the Office Action, and methods of administering a hydrogel to a mammal are exemplified in Applicant's application, e.g., see page 7, lines 23-27.

With respect to the enablement rejection, it is well established under 35 U.S.C. §112 ¶ 1, that "[t]he test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with

information known in the art without undue experimentation." *United States v. Teletronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1986). The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976); MPEP § 2164.01. Applicant respectfully submits that skilled artisans would have been able to practice, without undue experimentation, the invention of claim 17, prior to its amendment herein, with the knowledge of Applicant's specification.

Nonetheless, in the interest of expediting prosecution, Applicant amended independent claim 17, as discussed at the interview. Thus, claim 17, from which all other currently pending and examined claims depend, has been amended to recite a method for replacing, mimicking or augmenting the function of cartilage, synovial fluid or both. This recitation is fully supported in the specification and the Examiner indicated that such a claim would be allowable in the interview of December 9, 2004. Moreover, because the claim no longer recites a treatment of arthritis, the rejections are moot. Therefore, Applicant respectfully requests that the rejections be withdrawn.

CONCLUSION

For at least the reasons stated above, claims 17-26 and 36-39 are in condition for allowance. Accordingly, Applicant respectfully requests that the Application be allowed and passed to issue.

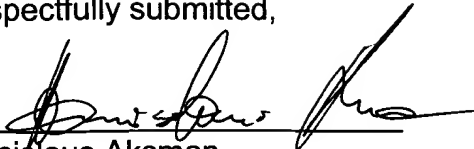
In the event any outstanding issues remain, Applicant would appreciate the courtesy of a telephone call to Applicant's undersigned representative to resolve such issues in an expeditious manner.

It is believed that no additional fees are due. However, in the event it is determined by the PTO that a discrepancy exists between the amount enclosed and the amount due, the Commissioner is authorized to debit or credit the undersigned's Deposit Account No. 50-0206 accordingly.

Appln. No.: 09/938,668
Petition for One-Month Extension of Time,
Statement of Substance of Interview Under
37 C.F.R. § 1.133 & Amendment Under
37 C.F.R. §1.111, Dated: January 7, 2005

Date: January 7, 2005

Respectfully submitted,

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